K121223

MAY 15 2012

5. 510(k) Summary

This summary of safety and effectiveness is provided as part of the Premarket Notification in compliance with 21CFR. Part 807, Subpart E, Section 807.92

1) Submitter's name, address, telephone number, contact person

Philips Ultrasound, Inc.
3000 Minuteman Road
Andover, MA
Penny Greco, Regulatory Affairs Specialist
Telephone: (978) 659-4615
Facsimile: (978) 975-7324
E-mail: penny.greco@philips.com

Date prepared: April 4, 2012

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name:	Picture Archiving and Communications Systems Workstation
Proprietary Name:	QLAB Quantification Software with FHN & VPQ
Classification Name:	CFR 892.2050, system, image processing, radiological, Product code LLZ, Class II

3) Substantially Equivalent Devices

Philips Ultrasound believes that the QLAB software with

- Fetal Heart Navigator (FHN) plug-in is substantially equivalent to other commercially available products, including Philips QLAB MVQ (K070792) and GE's Voluson Expert 8 VCAD (K113758).
- Vascular Plaque Quantification (VPQ) plug-in is substantially equivalent to other commercially available products, including Philips QLAB ROI (K021966) and IMT's M'Ath® Std (K040686).

4) Device Description

The QLAB software application is available either as a stand-alone product that can function on a standard PC, a dedicated workstation, and on-board Philips' ultrasound

systems. It can be used for the on-line and off-line review and quantification of ultrasound studies.

QLAB Quantification software now includes two new plug-in applications: Fetal Heart Navigator (FHN) and Vascular Plaque Quantification (VPQ).

Fetal Heart Navigator

The Fetal Heart Navigator (FHN) plug-in provides a semi-automated alignment of the fetal heart from a 4D acquisition and a protocol that steps users through the standard views. The objective of the protocol is to obtain the standard set of views that best reveal the most common fetal heart anomalies. The purpose of the FHN plug-in is for visualization The Fetal Heart Navigator tools do not produce quantitative data or measurements.

Vascular Plaque Quantification

The Vascular Plaque Quantification (VPQ) plug-in provides protocol-driven tools for performing a semi-automated analysis of plaques in the carotid artery. The clinical results include the location of the maximum reduction site, the percentage of stenosis, and the plaque volume in the entire image.

5) Intended Use

QLAB Quantification software is a software application package. It is designed to view and quantify image data acquired on Philips Healthcare ultrasound products.

6) Technological comparison to predicate devices

QLAB's FHN is similar to the QLAB MVQ in that users are able to rotate an image to a desired view. While MVQ requires the user to place reference points to finish a trace, FHN finds the center of the heart and ductal arch and then displays the ductal arch view. Similar to GE's VCAD, the QLAB Fetal Heart Navigator (FHN) feature is a tool that helps guide the user through the process of obtaining standard views used for fetal heart assessment: 4-Chamber, LVOT, and RVOT. Both FHN and VCAD comply with the recommended standard screening exam of the fetal heart as outlined by AIUM, ACOG, ACR and ISOUG.

Similar to the QLAB ROI plug-in, VPQ creates ROIs and can then measure the area of arbitrarily sized/shaped ROIs. Both the QLAB VPQ plug-in and the IMT M'Ath software automate plaque visualization and characterization. Both process Ultrasound images.

7) Non-clinical performance data

No performance standards for PACS systems or components have been issued under the authority of Section 514. The FHN and VPQ plug-ins were tested in accordance with Philips verification and validation processes. Quality assurance measures were applied to the system design and development, including:

- Risk Analysis
- Product Specifications
- Design Reviews
- Verification & Validation

Summary of Clinical Tests:
The subject of this premarket submission, QLAB Quantification software with VPQ and FHN did not require clinical studies to support substantial equivalence.

Conclusion:
Verification and validation testing concluded that the Fetal Heart Navigator and Vascular Plaque Quantification plug-ins are safe and effective and introduced no new risks.

8) General Safety and Effectiveness Concerns

The device labeling contains operating instructions for the safe and effective use of the QLAB software with the Fetal Heart Navigator and Vascular Plaque Quantification plug-ins.

9) Conclusions

The QLAB Quantification Software with Fetal Heart Navigator and Vascular Plaque Quantification incorporate components common to all image viewing systems for the display, manipulation and quantification tasks within a clinical setting. Software development for the QLAB software follows documented processes for software design, verification and validation testing. A risk assessment was completed to identify potential design hazards that could cause an error or injury based on the use of the quantification results. Appropriate steps have been taken to control all identified risks for this type of image display and quantification product. Verification and validation testing of the QLAB Quantification software with Fetal Heart Navigator and Vascular Plaque Quantification indicate no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Philips Ultrasound, Inc.
% Mr. Mark Job
Third Party Consultant
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

MAY 15 2012

Re: K121223
Trade/Device Name: QLAB Quantification Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 10, 2012
Received: May 14, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device Name: QLAB Quantification Software

Indications for Use:

QLAB Quantification Software is a software application package. It is designed to view and quantify image data acquired on Philips Healthcare ultrasound products.

Prescription Use X AND/OR **Over-the-counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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